DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Veterinary Medicine	**Protocol for Non-clinical and Effectiveness Studies**	Form Approved: OMB No. Expiration Date: 00/00/00

Submit this notice electronically to:
Food and Drug Administration
Center for Veterinary Medicine (HFV-)
7500 Standish Place
Rockville, Maryland 20855
(E-mail:cvmdcu@cvm.fda.gov)

DATE: **01/01/2002**
DOCUMENT ID: **INAD** **0**
STUDY / TRIAL ID: **Study ID**
TYPE OF STUDY: ☐ Pivotal ☐ Non-pivotal

The sponsor, **Company Name**, submits a protocol for use of an investigational new animal drug. Protocols for nonclinical laboratory studies (safety studies) are required under 21 CFR 58.120. Protocols for adequate and well-controlled effectiveness studies are required under 21 CFR 514.117(b). Sponsors may request that CVM review protocols for safety and effectiveness studies of new animal drugs. This information is submitted in electronic form.

I. Requesting Protocol CVM Review Yes ☐ No ☐

1. DRUG NAME(S):
   Established name(s): **Established Name of Drugs (if multiple, please separate by commas)**
   Trade name(s): **Trade Name**
2. PROTOCOL TITLE
   a. Short Abstract Title (80 characters): **Short Abstract Title**
   b. Full Title (256 characters): **Study Title**
   c. Version Number (If Applicable): **Version Number**
3. PROTOCOL PREVIOUSLY SUBMITTED TO CVM: ☐ YES ☐ NO
   a. If Yes, is the Protocol currently under review in CVM ☐ Date submitted to CVM: **01/01/2002** CVM submission number: **E** **0**
   b. Or, has the Protocol been previously reviewed by CVM ☐ Date submitted to CVM: **01/01/2002** CVM submission number: **E** **0**

II. Sponsor Information

1. NAME: **Company Name**
2. ADDRESS: **Applicant Address First Line**
   Applicant Address Second Line
   City **State** **00000-0000**
3. CONTACT NAME: **Contact Name**
4. CONTACT PHONE NUMBER: **(000) 000-0000**
5. CONTACT FAX NUMBER: **(000) 000-0000**
6. CONTACT E-MAIL ADDRESS: **Email Address**

SPONSOR SIGNATURE: (Adobe self sign)

III. Comments

Please enter any relevant comments here

IV. Protocol

Insert Submission **Add Password** **Mail to**